

AMENDED IN ASSEMBLY MAY 28, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1306

Introduced by Assembly Member Burke
(Coauthor: Assembly Member Mark Stone)

February 27, 2015

An act to amend Sections 650.01, 2725.1, 2746.2, 2746.5, 2746.51, 2746.52, 4061, 4076, and 4170 of, and to add Section 2746.6 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1306, as amended, Burke. Healing arts: certified nurse-midwives: scope of practice.

(1) Existing law, the Nursing Practice Act, provides for the licensure and regulation of the practice of nursing by the Board of Registered Nursing and authorizes the board to issue a certificate to practice nurse-midwifery to a person who meets educational standards established by the board or the equivalent of those educational standards. The act makes the violation of any of its provisions a misdemeanor punishable upon conviction by imprisonment in the county jail for not less than 10 days nor more than one year, or by a fine of not less than \$20 nor more than \$1,000, or by both that fine and imprisonment.

This bill would additionally require an applicant for a certificate to practice nurse-midwifery to provide evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board. This bill would also require the board to create and appoint a Nurse-Midwifery Advisory Council consisting of certified nurse-midwives in good standing with experience in hospital and nonhospital practice settings, a nurse-midwife educator,

as specified, and a consumer of midwifery care. This bill would require the council to make recommendations to the board on all matters related to nurse-midwifery practice, education, and other matters specified by the board, and would require the council to meet regularly, but at least twice a year. *This bill would also prohibit corporations and other artificial legal entities from having professional rights, privileges, or powers under the act, except as specified.*

(2) The act authorizes a certified nurse-midwife, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother, and immediate care for the newborn, and provides that the practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal.

This bill would delete those provisions and would instead authorize a certified nurse-midwife to manage a full range of primary health care services for women from adolescence beyond menopause, including, but not limited to, gynecologic and family planning services. The bill would authorize a certified nurse-midwife to practice in all settings, including, but not limited to, a home. This bill would declare that the practice of nurse-midwifery within a health care system provides for consultation, collaboration, or referral as indicated by the health status of the client and the resources of the medical personnel available in the setting of care, and would provide that the practice of nurse-midwifery emphasizes informed consent, preventive care, and early detection and referral of complications to a physician and surgeon. This bill would authorize a certified nurse-midwife to provide peripartum care in an out-of-hospital setting to low-risk women with uncomplicated singleton-term pregnancies who are expected to have uncomplicated birth.

(3) The act authorizes a certified nurse-midwife to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered consistently with the certified nurse-midwife's educational preparation in specified facilities and clinics, and only in accordance with standardized procedures and protocols, as specified.

This bill would delete the requirement that drugs or devices are furnished or ordered in accordance with standardized procedures and

protocols. The bill would authorize a certified nurse-midwife to furnish and order drugs or devices in connection with care rendered in a home, and would authorize a certified nurse-midwife to directly procure supplies and devices, to order, obtain, and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and that are consistent with nurse-midwifery education preparation.

(4) The act also authorizes a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a licensed acute care hospital and a licensed alternate birth center, if certain requirements are met, including, but not limited to, that episiotomies are performed pursuant to protocols developed and approved by the supervising physician and surgeon.

This bill would also authorize a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a patient's home, and would delete all requirements that those procedures be performed pursuant to protocols developed and approved by the supervising physician and surgeon. The bill would require a certified nurse-midwife to provide emergency care to a patient during times when a physician and surgeon is unavailable.

This bill would provide that a consultative relationship between a certified nurse-midwife and a physician and surgeon by it self is not a basis for finding the physician and surgeon liable for any acts or omissions on the part of the certified nurse-midwife. The bill would also update cross-references as needed.

(5) Because the act makes a violation of any of its provisions a misdemeanor, this bill would expand the scope of an existing crime and therefore this bill would impose a state-mandated local program.

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(6) Existing law prohibits a licensee, as defined, from referring a person for laboratory, diagnostic, nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or entity that receives the referral, and makes a violation of that prohibition punishable as a misdemeanor. Under existing law the Medical Board of California is required to review the facts and circumstances of any conviction for violating the prohibition, and to

take appropriate disciplinary action if the licensee has committed unprofessional conduct.

This bill would include a certified nurse-midwife under the definition of a licensee, which would expand the scope of an existing crime and therefore impose a state-mandated local program. The bill would also require the Board of Registered Nursing to review the facts and circumstances of any conviction of a certified nurse-midwife for violating that prohibition, and would require the board to take appropriate disciplinary action if the certified nurse-midwife has committed unprofessional conduct.

(7)The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 *SECTION 1. Section 650.01 of the Business and Professions*
- 2 *Code is amended to read:*
- 3 650.01. (a) Notwithstanding Section 650, or any other
- 4 ~~provision of~~ law, it is unlawful for a licensee to refer a person for
- 5 laboratory, diagnostic nuclear medicine, radiation oncology,
- 6 physical therapy, physical rehabilitation, psychometric testing,
- 7 home infusion therapy, or diagnostic imaging goods or services if
- 8 the licensee or his or her immediate family has a financial interest
- 9 with the person or in the entity that receives the referral.
- 10 (b) For purposes of this section and Section 650.02, the
- 11 following shall apply:
- 12 (1) “Diagnostic imaging” includes, but is not limited to, all
- 13 X-ray, computed axial tomography, magnetic resonance imaging
- 14 nuclear medicine, positron emission tomography, mammography,
- 15 and ultrasound goods and services.
- 16 (2) A “financial interest” includes, but is not limited to, any
- 17 type of ownership interest, debt, loan, lease, compensation,
- 18 remuneration, discount, rebate, refund, dividend, distribution,
- 19 subsidy, or other form of direct or indirect payment, whether in
- 20 money or otherwise, between a licensee and a person or entity to

1 whom the licensee refers a person for a good or service specified
2 in subdivision (a). A financial interest also exists if there is an
3 indirect financial relationship between a licensee and the referral
4 recipient including, but not limited to, an arrangement whereby a
5 licensee has an ownership interest in an entity that leases property
6 to the referral recipient. Any financial interest transferred by a
7 licensee to any person or entity or otherwise established in any
8 person or entity for the purpose of avoiding the prohibition of this
9 section shall be deemed a financial interest of the licensee. For
10 purposes of this paragraph, “direct or indirect payment” shall not
11 include a royalty or consulting fee received by a physician and
12 surgeon who has completed a recognized residency training
13 program in orthopedics from a manufacturer or distributor as a
14 result of his or her research and development of medical devices
15 and techniques for that manufacturer or distributor. For purposes
16 of this paragraph, “consulting fees” means those fees paid by the
17 manufacturer or distributor to a physician and surgeon who has
18 completed a recognized residency training program in orthopedics
19 only for his or her ongoing services in making refinements to his
20 or her medical devices or techniques marketed or distributed by
21 the manufacturer or distributor, if the manufacturer or distributor
22 does not own or control the facility to which the physician is
23 referring the patient. A “financial interest” shall not include the
24 receipt of capitation payments or other fixed amounts that are
25 prepaid in exchange for a promise of a licensee to provide specified
26 health care services to specified beneficiaries. A “financial interest”
27 shall not include the receipt of remuneration by a medical director
28 of a hospice, as defined in Section 1746 of the Health and Safety
29 Code, for specified services if the arrangement is set out in writing,
30 and specifies all services to be provided by the medical director,
31 the term of the arrangement is for at least one year, and the
32 compensation to be paid over the term of the arrangement is set
33 in advance, does not exceed fair market value, and is not
34 determined in a manner that takes into account the volume or value
35 of any referrals or other business generated between parties.

36 (3) For the purposes of this section, “immediate family” includes
37 the spouse and children of the licensee, the parents of the licensee,
38 and the spouses of the children of the licensee.

39 (4) “Licensee” means a physician as defined in Section 3209.3
40 of the Labor-Code, *Code*, and a certified nurse-midwife as defined

1 *in Article 2.5 (commencing with Section 2746) of Chapter 6 of*
2 *Division 2 of the Business and Professions Code.*

3 (5) "Licensee's office" means either of the following:

4 (A) An office of a licensee in solo practice.

5 (B) An office in which services or goods are personally provided
6 by the licensee or by employees in that office, or personally by
7 independent contractors in that office, in accordance with other
8 provisions of law. Employees and independent contractors shall
9 be licensed or certified when licensure or certification is required
10 by law.

11 (6) "Office of a group practice" means an office or offices in
12 which two or more licensees are legally organized as a partnership,
13 professional corporation, or not-for-profit corporation, licensed
14 pursuant to subdivision (a) of Section 1204 of the Health and Safety
15 Code, for which all of the following apply:

16 (A) Each licensee who is a member of the group provides
17 substantially the full range of services that the licensee routinely
18 provides, including medical care, consultation, diagnosis, or
19 treatment through the joint use of shared office space, facilities,
20 equipment, and personnel.

21 (B) Substantially all of the services of the licensees who are
22 members of the group are provided through the group and are
23 billed in the name of the group and amounts so received are treated
24 as receipts of the group, except in the case of a multispecialty
25 clinic, as defined in subdivision (l) of Section 1206 of the Health
26 and Safety Code, physician services are billed in the name of the
27 multispecialty clinic and amounts so received are treated as receipts
28 of the multispecialty clinic.

29 (C) The overhead expenses of, and the income from, the practice
30 are distributed in accordance with methods previously determined
31 by members of the group.

32 (c) It is unlawful for a licensee to enter into an arrangement or
33 scheme, such as a cross-referral arrangement, that the licensee
34 knows, or should know, has a principal purpose of ensuring
35 referrals by the licensee to a particular entity that, if the licensee
36 directly made referrals to that entity, would be in violation of this
37 section.

38 (d) No claim for payment shall be presented by an entity to any
39 individual, third party payer, or other entity for a good or service
40 furnished pursuant to a referral prohibited under this section.

1 (e) No insurer, self-insurer, or other payer shall pay a charge or
2 lien for any good or service resulting from a referral in violation
3 of this section.

4 (f) A licensee who refers a person to, or seeks consultation from,
5 an organization in which the licensee has a financial interest, other
6 than as prohibited by subdivision (a), shall disclose the financial
7 interest to the patient, or the parent or legal guardian of the patient,
8 in writing, at the time of the referral or request for consultation.

9 (1) If a referral, billing, or other solicitation is between one or
10 more licensees who contract with a multispecialty clinic pursuant
11 to subdivision (l) of Section 1206 of the Health and Safety Code
12 or who conduct their practice as members of the same professional
13 corporation or partnership, and the services are rendered on the
14 same physical premises, or under the same professional corporation
15 or partnership name, the requirements of this subdivision may be
16 met by posting a conspicuous disclosure statement at the
17 registration area or by providing a patient with a written disclosure
18 statement.

19 (2) If a licensee is under contract with the Department of
20 Corrections or the California Youth Authority, and the patient is
21 an inmate or parolee of either respective department, the
22 requirements of this subdivision shall be satisfied by disclosing
23 financial interests to either the Department of Corrections or the
24 California Youth Authority.

25 (g) A violation of subdivision (a) shall be a misdemeanor. ~~The~~
26 *In the case of a licensee who is a physician, the* Medical Board of
27 California shall review the facts and circumstances of any
28 conviction pursuant to subdivision (a) and take appropriate
29 disciplinary action if the licensee has committed unprofessional
30 conduct. *In the case of a licensee who is a certified nurse-midwife,*
31 *the Board of Registered Nursing shall review the facts and*
32 *circumstances of any conviction pursuant to subdivision (a) and*
33 *take appropriate disciplinary action if the licensee has committed*
34 *unprofessional conduct.* Violations of this section may also be
35 subject to civil penalties of up to five thousand dollars (\$5,000)
36 for each offense, which may be enforced by the Insurance
37 Commissioner, Attorney General, or a district attorney. A violation
38 of subdivision (c), (d), or (e) is a public offense and is punishable
39 upon conviction by a fine not exceeding fifteen thousand dollars
40 (\$15,000) for each violation and appropriate disciplinary action,

1 including revocation of professional licensure, by the Medical
2 Board of ~~California~~ *California, the Board of Registered Nursing*,
3 or other appropriate governmental agency.

4 (h) This section shall not apply to referrals for services that are
5 described in and covered by Sections 139.3 and 139.31 of the
6 Labor Code.

7 (i) This section shall become operative on January 1, 1995.

8 **SECTION 1.**

9 *SEC. 2.* Section 2725.1 of the Business and Professions Code
10 is amended to read:

11 2725.1. (a) Notwithstanding any other law, a registered nurse
12 may dispense drugs or devices upon an order by a licensed
13 physician and surgeon or an order by a certified nurse-midwife,
14 nurse practitioner, or physician assistant issued pursuant to Section
15 2746.51, 2836.1, or 3502.1, respectively, if the registered nurse is
16 functioning within a licensed primary care clinic as defined in
17 subdivision (a) of Section 1204 of, or within a clinic as defined in
18 subdivision (b), (c), (h), or (j) of Section 1206 of, the Health and
19 Safety Code.

20 (b) No clinic shall employ a registered nurse to perform
21 dispensing duties exclusively. No registered nurse shall dispense
22 drugs in a pharmacy, keep a pharmacy, open shop, or drugstore
23 for the retailing of drugs or poisons. No registered nurse shall
24 compound drugs. Dispensing of drugs by a registered nurse, except
25 a certified nurse-midwife who functions pursuant to Section
26 2746.51 or a nurse practitioner who functions pursuant to a
27 standardized procedure described in Section 2836.1, or protocol,
28 shall not include substances included in the California Uniform
29 Controlled Substances Act (Division 10 (commencing with Section
30 11000) of the Health and Safety Code). Nothing in this section
31 shall exempt a clinic from the provisions of Article 13
32 (commencing with Section 4180) of Chapter 9.

33 (c) This section shall not be construed to limit any other
34 authority granted to a certified nurse-midwife pursuant to Article
35 2.5 (commencing with Section 2746), to a nurse practitioner
36 pursuant to Article 8 (commencing with Section 2834), or to a
37 physician assistant pursuant to Chapter 7.7 (commencing with
38 Section 3500).

39 (d) This section shall not be construed to affect the sites or types
40 of health care facilities at which drugs or devices are authorized

1 to be dispensed pursuant to Chapter 9 (commencing with Section
2 4000).

3 ~~SEC. 2.~~

4 *SEC. 3.* Section 2746.2 of the Business and Professions Code
5 is amended to read:

6 2746.2. (a) Each applicant shall show by evidence satisfactory
7 to the board that he or she has met the educational standards
8 established by the board or has at least the equivalent thereof,
9 including evidence of current advanced level national certification
10 by a certifying body that meets standards established and approved
11 by the board.

12 (b) The board shall create and appoint a Nurse-Midwifery
13 Advisory Council consisting of certified nurse-midwives in good
14 standing with experience in hospital and nonhospital practice
15 settings, a nurse-midwife educator who has demonstrated
16 familiarity with consumer needs, collegial practice and
17 accompanied liability, and related educational standards in the
18 delivery of maternal-child health care, and a consumer of
19 midwifery care. The council shall make recommendations to the
20 board on all matters related to nurse-midwifery practice, education,
21 and other matters as specified by the board. The council shall meet
22 regularly, but at least twice a year.

23 (c) *Corporations and other artificial legal entities shall have*
24 *no professional rights, privileges, or powers. However, the Board*
25 *of Registered Nursing may in its discretion, after such investigation*
26 *and review of such documentary evidence as it may require, and*
27 *under regulations adopted by it, grant approval of the employment*
28 *of licensees on a salary basis by licensed charitable institutions,*
29 *foundations, or clinics, if no charge for professional services*
30 *rendered patients is made by any such institution, foundation, or*
31 *clinic.*

32 ~~SEC. 3.~~

33 *SEC. 4.* Section 2746.5 of the Business and Professions Code
34 is amended to read:

35 2746.5. (a) The certificate to practice nurse-midwifery
36 authorizes the holder to manage a full range of primary health care
37 services for women from adolescence to beyond menopause. These
38 services include, but are not limited to, primary health care,
39 gynecologic and family planning services, preconception care,
40 care during pregnancy, childbirth, and the postpartum period,

1 immediate care of the newborn, and treatment of male partners for
2 sexually transmitted infections. A certified nurse-midwife is
3 authorized to practice in all settings, including, but not limited to,
4 private practice, clinics, hospitals, birth centers, and homes.

5 (b) As used in this chapter, the practice of nurse-midwifery
6 within a health care system provides for consultation, collaboration,
7 or referral as indicated by the health status of the patient and the
8 resources and medical personnel available in the setting of care.
9 When providing peripartum care in out-of-hospital settings, the
10 certified nurse-midwife shall only provide care to low-risk women
11 with uncomplicated singleton-term pregnancies who are expected
12 to have an uncomplicated birth. The practice of nurse-midwifery
13 care emphasizes informed consent, preventive care, and early
14 detection and referral of complications to physicians and surgeons.
15 While practicing in a hospital setting, the certified nurse-midwife
16 shall collaboratively care for women with more complex health
17 needs.

18 (c) A certified nurse-midwife is not authorized to practice
19 medicine and surgery by the provisions of this chapter.

20 (d) Any regulations promulgated by a state department that
21 affect the scope of practice of a certified nurse-midwife shall be
22 developed in consultation with the board.

23 ~~SEC. 4.~~

24 *SEC. 5.* Section 2746.51 of the Business and Professions Code
25 is amended to read:

26 2746.51. (a) Neither this chapter nor any other law shall be
27 construed to prohibit a certified nurse-midwife from furnishing or
28 ordering drugs or devices, including controlled substances
29 classified in Schedule II, III, IV, or V under the California Uniform
30 Controlled Substances Act (Division 10 (commencing with Section
31 11000) of the Health and Safety Code), when the drugs or devices
32 are furnished or ordered related to the provision of any of the
33 following:

34 (1) Family planning services, as defined in Section 14503 of
35 the Welfare and Institutions Code.

36 (2) Routine health care or perinatal care, as defined in
37 subdivision (d) of Section 123485 of the Health and Safety Code.

38 (3) Care rendered, consistent with the certified nurse-midwife's
39 educational preparation or for which clinical competency has been
40 established and maintained, to persons within a facility specified

1 in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the
2 Health and Safety Code, a clinic as specified in Section 1204 of
3 the Health and Safety Code, a general acute care hospital as defined
4 in subdivision (a) of Section 1250 of the Health and Safety Code,
5 a licensed birth center as defined in Section 1204.3 of the Health
6 and Safety Code, or a special hospital specified as a maternity
7 hospital in subdivision (f) of Section 1250 of the Health and Safety
8 Code.

9 (4) Care rendered in a home pursuant to subdivision (a) of
10 Section 2746.5.

11 (b) (1) The furnishing or ordering of drugs or devices by a
12 certified nurse-midwife is conditional on the issuance by the board
13 of a number to the applicant who has successfully completed the
14 requirements of paragraph (2). The number shall be included on
15 all transmittals of orders for drugs or devices by the certified
16 nurse-midwife. The board shall maintain a list of the certified
17 nurse-midwives that it has certified pursuant to this paragraph and
18 the number it has issued to each one. The board shall make the list
19 available to the California State Board of Pharmacy upon its
20 request. Every certified nurse-midwife who is authorized pursuant
21 to this section to furnish or issue a drug order for a controlled
22 substance shall register with the United States Drug Enforcement
23 Administration.

24 (2) The board has certified in accordance with paragraph (1)
25 that the certified nurse-midwife has satisfactorily completed a
26 course in pharmacology covering the drugs or devices to be
27 furnished or ordered under this section. The board shall establish
28 the requirements for satisfactory completion of this paragraph.

29 (3) Certified nurse-midwives who are certified by the board and
30 hold an active furnishing number, who are currently authorized to
31 furnish Schedule II controlled substances, and who are registered
32 with the United States Drug Enforcement Administration shall
33 provide documentation of continuing education specific to the use
34 of Schedule II controlled substances in settings other than a hospital
35 based on standards developed by the board.

36 (c) Drugs or devices furnished or ordered by a certified
37 nurse-midwife may include Schedule II controlled substances
38 under the California Uniform Controlled Substances Act (Division
39 10 (commencing with Section 11000) of the Health and Safety
40 Code) when the drugs and devices are furnished or ordered in

1 accordance with requirements referenced in paragraphs (1) to (3),
2 inclusive, of subdivision (b).

3 (d) Furnishing of drugs or devices by a certified nurse-midwife
4 means the act of making a pharmaceutical agent or agents available
5 to the patient.

6 (e) “Drug order” or “order” for purposes of this section means
7 an order for medication or for a drug or device that is dispensed
8 to or for an ultimate user, issued by a certified nurse-midwife as
9 an individual practitioner, within the meaning of Section 1306.03
10 of Title 21 of the Code of Federal Regulations. Notwithstanding
11 any other law, (1) a drug order issued pursuant to this section shall
12 be treated in the same manner as a prescription of a physician; (2)
13 all references to “prescription” in this code and the Health and
14 Safety Code shall include drug orders issued by certified
15 nurse-midwives; and (3) the signature of a certified nurse-midwife
16 on a drug order issued in accordance with this section shall be
17 deemed to be the signature of a prescriber for purposes of this code
18 and the Health and Safety Code.

19 (f) A certified nurse-midwife is authorized to directly procure
20 supplies and devices, to order, obtain, and administer drugs and
21 diagnostic tests, to order laboratory and diagnostic testing, and to
22 receive reports that are necessary to his or her practice as a certified
23 nurse-midwife and consistent with nurse-midwifery education
24 preparation.

25 ~~SEC. 5.~~

26 *SEC. 6.* Section 2746.52 of the Business and Professions Code
27 is amended to read:

28 2746.52. (a) Notwithstanding Section 2746.5, the certificate
29 to practice nurse-midwifery authorizes the holder to perform and
30 repair episiotomies, and to repair first-degree and second-degree
31 lacerations of the perineum, in a licensed acute care hospital, as
32 defined in subdivision (a) of Section 1250 of the Health and Safety
33 Code, in a licensed alternate birth center, as defined in paragraph
34 (4) of subdivision (b) of Section 1204 of the Health and Safety
35 Code, and in a home pursuant to subdivision (a) of Section 2746.5.

36 (b) The certified nurse-midwife performing and repairing
37 first-degree and second-degree lacerations of the perineum shall
38 do both of the following:

39 (1) Ensure that all complications are referred to a physician and
40 surgeon immediately.

(2) Ensure immediate care of patients who are in need of care beyond the scope of practice of the certified ~~nurse-midwife~~, *nurse-midwife*, or provide emergency care for times when a physician and surgeon is not available.

~~SEC. 6.~~

SEC. 7. Section 2746.6 is added to the Business and Professions Code, to read:

2746.6. A consultative relationship between a certified nurse-midwife and a physician and surgeon shall not, by it self, provide the basis for finding a physician and surgeon liable for any act or omission of the certified nurse-midwife.

~~SEC. 7.~~

SEC. 8. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) A manufacturer's sales representative shall not distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. However, a certified nurse-midwife who functions pursuant to Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor, if applicable, receiving the samples pursuant

1 to this section, the date of receipt, and the name and quantity of
2 the dangerous drugs or dangerous devices provided. These records
3 shall be preserved by the supplier with the records required by
4 Section 4059.

5 (c) Nothing in this section is intended to expand the scope of
6 practice of a certified nurse-midwife, nurse practitioner, physician
7 assistant, or naturopathic doctor.

8 ~~SEC. 8.~~

9 *SEC. 9.* Section 4076 of the Business and Professions Code is
10 amended to read:

11 4076. (a) A pharmacist shall not dispense any prescription
12 except in a container that meets the requirements of state and
13 federal law and is correctly labeled with all of the following:

14 (1) Except when the prescriber or the certified nurse-midwife
15 who functions pursuant to Section 2746.51, the nurse practitioner
16 who functions pursuant to a standardized procedure described in
17 Section 2836.1 or protocol, the physician assistant who functions
18 pursuant to Section 3502.1, the naturopathic doctor who functions
19 pursuant to a standardized procedure or protocol described in
20 Section 3640.5, or the pharmacist who functions pursuant to a
21 policy, procedure, or protocol pursuant to Section 4052.1, 4052.2,
22 or 4052.6 orders otherwise, either the manufacturer's trade name
23 of the drug or the generic name and the name of the manufacturer.
24 Commonly used abbreviations may be used. Preparations
25 containing two or more active ingredients may be identified by
26 the manufacturer's trade name or the commonly used name or the
27 principal active ingredients.

28 (2) The directions for the use of the drug.

29 (3) The name of the patient or patients.

30 (4) The name of the prescriber or, if applicable, the name of the
31 certified nurse-midwife who functions pursuant to Section 2746.51,
32 the nurse practitioner who functions pursuant to a standardized
33 procedure described in Section 2836.1 or protocol, the physician
34 assistant who functions pursuant to Section 3502.1, the naturopathic
35 doctor who functions pursuant to a standardized procedure or
36 protocol described in Section 3640.5, or the pharmacist who
37 functions pursuant to a policy, procedure, or protocol pursuant to
38 Section 4052.1, 4052.2, or 4052.6.

39 (5) The date of issue.

1 (6) The name and address of the pharmacy, and prescription
2 number or other means of identifying the prescription.

3 (7) The strength of the drug or drugs dispensed.

4 (8) The quantity of the drug or drugs dispensed.

5 (9) The expiration date of the effectiveness of the drug
6 dispensed.

7 (10) The condition or purpose for which the drug was prescribed
8 if the condition or purpose is indicated on the prescription.

9 (11) (A) Commencing January 1, 2006, the physical description
10 of the dispensed medication, including its color, shape, and any
11 identification code that appears on the tablets or capsules, except
12 as follows:

13 (i) Prescriptions dispensed by a veterinarian.

14 (ii) An exemption from the requirements of this paragraph shall
15 be granted to a new drug for the first 120 days that the drug is on
16 the market and for the 90 days during which the national reference
17 file has no description on file.

18 (iii) Dispensed medications for which no physical description
19 exists in any commercially available database.

20 (B) This paragraph applies to outpatient pharmacies only.

21 (C) The information required by this paragraph may be printed
22 on an auxiliary label that is affixed to the prescription container.

23 (D) This paragraph shall not become operative if the board,
24 prior to January 1, 2006, adopts regulations that mandate the same
25 labeling requirements set forth in this paragraph.

26 (b) If a pharmacist dispenses a prescribed drug by means of a
27 unit dose medication system, as defined by administrative
28 regulation, for a patient in a skilled nursing, intermediate care, or
29 other health care facility, the requirements of this section will be
30 satisfied if the unit dose medication system contains the
31 aforementioned information or the information is otherwise readily
32 available at the time of drug administration.

33 (c) If a pharmacist dispenses a dangerous drug or device in a
34 facility licensed pursuant to Section 1250 of the Health and Safety
35 Code, it is not necessary to include on individual unit dose
36 containers for a specific patient, the name of the certified
37 nurse-midwife who functions pursuant to Section 2746.51, the
38 nurse practitioner who functions pursuant to a standardized
39 procedure described in Section 2836.1 or protocol, the physician
40 assistant who functions pursuant to Section 3502.1, the naturopathic

1 doctor who functions pursuant to a standardized procedure or
2 protocol described in Section 3640.5, or the pharmacist who
3 functions pursuant to a policy, procedure, or protocol pursuant to
4 Section 4052.1, 4052.2, or 4052.6.

5 (d) If a pharmacist dispenses a prescription drug for use in a
6 facility licensed pursuant to Section 1250 of the Health and Safety
7 Code, it is not necessary to include the information required in
8 paragraph (11) of subdivision (a) when the prescription drug is
9 administered to a patient by a person licensed under the Medical
10 Practice Act (Chapter 5 (commencing with Section 2000)), the
11 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
12 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
13 with Section 2840)), who is acting within his or her scope of
14 practice.

15 ~~SEC. 9.~~

16 *SEC. 10.* Section 4170 of the Business and Professions Code
17 is amended to read:

18 4170. (a) A prescriber shall not dispense drugs or dangerous
19 devices to patients in his or her office or place of practice unless
20 all of the following conditions are met:

21 (1) The dangerous drugs or dangerous devices are dispensed to
22 the prescriber's own patient, and the drugs or dangerous devices
23 are not furnished by a nurse or physician attendant.

24 (2) The dangerous drugs or dangerous devices are necessary in
25 the treatment of the condition for which the prescriber is attending
26 the patient.

27 (3) The prescriber does not keep a pharmacy, open shop, or
28 drugstore, advertised or otherwise, for the retailing of dangerous
29 drugs, dangerous devices, or poisons.

30 (4) The prescriber fulfills all of the labeling requirements
31 imposed upon pharmacists by Section 4076, all of the
32 recordkeeping requirements of this chapter, and all of the packaging
33 requirements of good pharmaceutical practice, including the use
34 of childproof containers.

35 (5) The prescriber does not use a dispensing device unless he
36 or she personally owns the device and the contents of the device,
37 and personally dispenses the dangerous drugs or dangerous devices
38 to the patient packaged, labeled, and recorded in accordance with
39 paragraph (4).

1 (6) The prescriber, prior to dispensing, offers to give a written
2 prescription to the patient that the patient may elect to have filled
3 by the prescriber or by any pharmacy.

4 (7) The prescriber provides the patient with written disclosure
5 that the patient has a choice between obtaining the prescription
6 from the dispensing prescriber or obtaining the prescription at a
7 pharmacy of the patient's choice.

8 (8) A certified nurse-midwife who functions pursuant to Section
9 2746.51, a nurse practitioner who functions pursuant to a
10 standardized procedure described in Section 2836.1, or protocol,
11 a physician assistant who functions pursuant to Section 3502.1, or
12 a naturopathic doctor who functions pursuant to Section 3640.5,
13 may hand to a patient of the supervising physician and surgeon a
14 properly labeled prescription drug prepackaged by a physician and
15 surgeon, a manufacturer as defined in this chapter, or a pharmacist.

16 (b) The Medical Board of California, the State Board of
17 Optometry, the Bureau of Naturopathic Medicine, the Dental Board
18 of California, the Osteopathic Medical Board of California, the
19 Board of Registered Nursing, the Veterinary Medical Board, and
20 the Physician Assistant Committee shall have authority with the
21 California State Board of Pharmacy to ensure compliance with
22 this section, and those boards are specifically charged with the
23 enforcement of this chapter with respect to their respective
24 licensees.

25 (c) "Prescriber," as used in this section, means a person, who
26 holds a physician's and surgeon's certificate, a license to practice
27 optometry, a license to practice naturopathic medicine, a license
28 to practice dentistry, a license to practice veterinary medicine, or
29 a certificate to practice podiatry, and who is duly registered by the
30 Medical Board of California, the State Board of Optometry, the
31 Bureau of Naturopathic Medicine, the Dental Board of California,
32 the Veterinary Medical Board, or the Board of Osteopathic
33 Examiners of this state.

34 ~~SEC. 10.~~

35 *SEC. 11.* No reimbursement is required by this act pursuant to
36 Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 for a crime or infraction, within the meaning of Section 17556 of

- 1 the Government Code, or changes the definition of a crime within
- 2 the meaning of Section 6 of Article XIII B of the California
- 3 Constitution.

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